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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,442	02/26/2004	Julia E. Novak	99-16D3	8214

10117 7590 09/14/2007
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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

MAIL DATE	DELIVERY MODE
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09/14/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/787,442

Applicant(s)

NOVAK ET AL.

Examiner

Jegatheesan Seharaseyon, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 10-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 10-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicant's remarks and amendments filed 7/02/2007. Claims 1-12 are pending. Claims 2, 10 and 11 have been amended. Claims 3-9 are withdrawn pursuant to a restriction requirement. Therefore claims 1, 2 and 10-12 are examined.

2. Any objection or rejection of record, which is not expressly repeated in this action, has been overcome by Applicant's response and withdrawn.

3. The Office notes that Applicant has amended the specification to remove embedded hyperlinks and capitalize trademarks.

4. Applicant has clarified reference A3 on the IDS filed July 27, 2006 to be a reissue Application.

Claim Rejections - 35 USC § 112, 1st paragraph maintained

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5a. The rejection of claims 1, 2 and 10-12 under 35 U.S.C. 112, first paragraph, because the specification while enabling for a fusion protein comprising polypeptide of SEQ ID NO: 2, does not reasonably provide enablement for all possible fusion proteins comprising variants and fragments including those that are at least 90% or 95% identical to SEQ ID NO: 2 is maintained for reasons set forth in the Office Action dated 1/12/07 pages 4-7. Specifically, claims 1, 10 and 12 recite the phrase "a polypeptide"

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and thus, are broadly interpreted by the Examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length (see specification page 56).

Applicant is essentially arguing that the Office is interpreting the claims unreasonably broad. Applicant is arguing that the broadest possible interpretation of language is not necessarily the broadest reasonable interpretation. Applicant contends that the USPTO's new interpretation of the contested language of the claims renders the claim so broad as it reads on any amino acid sequence that has six or more residues. Applicant argues that this interpretation is unreasonable. In addition, such an interpretation of the claims is entirely inconsistent with the specification, and hence cannot be reasonable. In addition, Applicant assert that support for such an interpretation is not found in the application, for the simple reason that applicants never intended to make such a claim and therefore never described or enabled amino acid sequences that were six or more amino acid residues long. Further it is asserted that it is difficult to understand why an interpretation that was reasonable previously has been replaced by an interpretation that is contrary to the specification and claims of the patent. Applicant discusses the Office interpretation of the claims extensively on pages 9-13 of the response, specifically the inclusion of the fragments and variants. Applicant asserts that they describe the claimed fragments and variants both structurally and functionally. Applicant also discusses various fragments that are claimed and the biological function of the polypeptides (see page 12 of the response). Applicant's arguments have been fully considered but are not found to be persuasive.

Contrary to Applicant's assertion that Office interpretation is broad and unreasonable, the Office is interpreting "a" as an indefinite article to read on (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2. In contrast "the" is considered definite article and thus is interpreted to be limited to the sequence of interest only. In addition, the specification of the instant invention defines a polypeptide as a polymer of amino acid residues joined by peptide bonds, whether produced naturally or synthetically. Further, the specification teaches that polypeptides of less than about 10 amino acid residues are commonly referred to as "peptide". Although, the specification clearly identifies various fragments, the Office is interpreting the claims to read on for example, polypeptide fragment and variants that are 6 amino acids or longer because of the indefinite article "a". In addition, there is no enabling disclosure for variants and fragments that 90% or 95% identical to mature polypeptide or the polypeptide fragments that binds the receptor of SEQ ID NO 115. Although, the specification discloses the biological function of the α 11 ligand, there is no correlation between the various variants/fragments and the biological functions disclosed. In the absence of further guidance, these experiments (assay for proliferation, binding assays etc.) would be more than routine experimentation for one of skilled in the art. It will require trial and error experimentation to identify the variants and fragments that are functional. Therefore, the rejection of record is maintained.

5b. The rejection of claims 1, 2 and 10-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention. *This is a written description rejection* is maintained for reasons set forth in the Office Action dated 1/12/07 pages 8-9. The specification does not disclose all possible fragments and variants including those that are at least 90% or 95% identical to SEQ ID NO: 2 contemplated by the Applicant. Specifically, claims 1, 10 and 12 lack written description support for the language reciting the phrases and “ a polypeptide” and thus, are broadly interpreted by the Examiner as reading upon: (i) protein variants with any number of deletions, substitutions, or additions and (ii) fragments of SEQ ID NO: 2, including sequences only 6 amino acids in length (see specification page 56).

Applicant has argued both the enablement and written description together (see 4a). Applicant's arguments have been fully considered but are not found to be persuasive. The Office has responded to the Applicant's arguments above in paragraph 4a. Therefore, the rejection of record is maintained.

5c. The rejection of claims 9-11 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for composition of polypeptide of SEQ ID NO: 2 or polypeptide comprising residues 32 to 162 of SEQ ID NO: 2 (alpha11 ligand) does not reasonably provide enablement for pharmaceutical composition comprising polypeptide that is 90% or 95% identical to residues 32 to 162 of SEQ ID NO: 2 or residues 32 to 162 of SEQ ID NO: 2 is maintained for reasons set forth in Office Action dated 1/17/07 pages 9-10. Applicant has not traversed the rejection. Therefore, the rejection of record is maintained.

Double Patenting

6. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

6a. The provisional rejection of claims 1 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 of copending Application No. 11/ 551, 344 is maintained for reasons set forth in Office Action dated 1/12/07 page 110. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant has not presented any arguments to the double patenting rejection. **Claim 1 of this application conflict with claim 1 Application No. 11/551, 344. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to**

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either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The rejection of record is maintained.

6b. The provisional rejection of claims 1 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 of copending Application No. 11/ 551, 368 is maintained for reasons set forth in Office Action dated 1/12/07 page 110. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant has not presented any arguments to the double patenting rejection.

Claim 1 of this application conflict with claim 1 of Application No. 11/551, 368. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The rejection of record is maintained.

6c. The provisional rejection of claims 1 under 35 U.S.C. 101 as claiming the same invention as that of claims 1 of copending Application No. 11/ 551, 362 is maintained for reasons set forth in Office Action dated 1/12/07 page 110. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Applicant has not presented any arguments to the double patenting rejection.

Claim 1 of this application conflict with claim 1 of Application No. 11/551, 362. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The rejection of record is maintained.

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The provisional rejection of claims 1, 10 and 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending

Application No. 11/551, 820 in view of Beckmann et al. (U.S. Patent No. 5, 573, 924) is maintained for reasons set forth in the Office Action dated 1/12/2007 pages 10-12.

Applicant has indicated that they will file a Terminal Disclaimer when the instant claims are allowable. However, since the instant claims are not allowable and no Terminal Disclaimer has been filed the provisional obviousness-type double patenting rejection is maintained.

Conclusion

8. No claims are allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS
Art Unit 1647,
September 4th, 2007.

CHRISTINE J. SAUD
PRIMARY EXAMINER

